A single course of pulmonary rehabilitation in the outpatient ambulatory care setting may be considered medically necessary for outpatient treatment of chronic pulmonary disease for patients with moderate to severe disease who are experiencing disabling symptoms and significantly diminished quality of life in spite of optimal medical management.

A single course of pulmonary rehabilitation may be considered medically necessary in an outpatient ambulatory care setting as a preoperative conditioning component for those considered appropriate candidates for lung volume reduction surgery and for lung transplantation (see Related Policies).

Multiple courses of pulmonary rehabilitation are considered investigational, either as maintenance therapy in patients who initially respond or in patients who fail to respond or whose response to an initial rehabilitation program has diminished over time.

Home-based pulmonary rehabilitation programs are considered investigational.

Pulmonary rehabilitation programs are considered medically necessary following lung transplantation.

Pulmonary rehabilitation programs are considered investigational following other types of lung surgery, included but not limited to lung volume reduction surgery and surgical resection of lung cancer.

Pulmonary rehabilitation programs are considered investigational in all other situations.

Related Policies

7.03.509 Solid Organ Transplants

Policy Guidelines

A pulmonary rehabilitation outpatient program is a comprehensive program that generally includes team
assessment, patient training, psychosocial intervention, exercise training, and follow-up. The overall length of the program and the total number of visits for each component may vary from program to program.

Team assessment includes input from a physician, respiratory care practitioner, nurse, and psychologist, among others.

Patient training includes breathing retraining, bronchial hygiene, medications, and proper nutrition.

Psychosocial intervention addresses support system and dependency issues.

Exercise training includes strengthening and conditioning and may include stair climbing, inspiratory muscle training, treadmill walking, cycle training (with or without ergometer), and supported and unsupported arm exercise training. Exercise conditioning is an essential component of pulmonary rehabilitation. Education in disease management techniques without exercise conditioning does not improve health outcomes of patients who have chronic obstructive pulmonary disease.

Follow-up to a comprehensive outpatient pulmonary rehabilitation program may include supervised home exercise conditioning.

Candidates for pulmonary rehabilitation should be medically stable and not limited by another serious or unstable medical condition. Contraindications to pulmonary rehabilitation include severe psychiatric disturbance (e.g., dementia, organic brain syndrome), and significant or unstable medical conditions (e.g., heart failure, acute cor pulmonale, substance abuse, significant liver dysfunction, metastatic cancer, disabling stroke).

<table>
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<tr>
<th>Coding</th>
<th>Description</th>
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<td>CPT</td>
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<tr>
<td>94799</td>
<td>Unlisted pulmonary service or procedure</td>
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<td>97799</td>
<td>Unlisted physical medicine/rehabilitation service or procedure</td>
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<td>HCPCS</td>
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<tr>
<td>G0237</td>
<td>Therapeutic procedures to increase strength or endurance of respiratory muscles, face-to-face, one-on-one, each 15 minutes (includes monitoring)</td>
</tr>
<tr>
<td>G0238</td>
<td>Therapeutic procedures to improve respiratory function, other than described by G0237, one-on-one, face-to-face, per 15 minutes (includes monitoring)</td>
</tr>
<tr>
<td>G0239</td>
<td>Therapeutic procedures to improve respiratory function or increase strength or endurance of respiratory muscles, 2 or more individuals (includes monitoring)</td>
</tr>
<tr>
<td>G0302</td>
<td>Preoperative pulmonary surgery services for preparation for LVRS, complete course of services, to include a minimum of 16 days of services</td>
</tr>
<tr>
<td>G0303</td>
<td>Preoperative pulmonary surgery services for preparation for LVRS, 10 to 15 days of services</td>
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<td>G0304</td>
<td>Preoperative pulmonary surgery services for preparation for LVRS, 1 to 9 days of services</td>
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<tr>
<td>G0305</td>
<td>Postdischarge pulmonary surgery services after LVRS, minimum of 6 days of services</td>
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<tr>
<td>G0424</td>
<td>Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session, up to 2 sessions per day</td>
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<td>S9473</td>
<td>Pulmonary rehabilitation program, nonphysician provider, per diem</td>
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Description

Pulmonary rehabilitation (PR) is a multidisciplinary approach to reducing symptoms and improving quality of life in patients with compromised lung function.

Background

The American Thoracic Society (ATS) and the European Respiratory Society (ERS) define PR as a “comprehensive intervention based on a thorough patient assessment followed by patient-tailored therapies that include, but are not limited to exercise training, education, and behavior change.” (1) PR programs are intended to improve the patient’s functioning and quality of life. Most study has focused on patients with COPD, although there has been some interest in PR in patients with asthma, cystic fibrosis, or bronchiectasis. According to a joint ATS/ERS statement issued in 2013, PR may be of value for conditions other than COPD (e.g., bronchiectasis, asthma, cystic fibrosis) in cases in which respiratory symptoms are associated with diminished functional capacity or reduced health-related quality of life. (1)
PR is also routinely offered to patients awaiting lung transplantation and lung volume reduction surgery. PR before lung surgery may stabilize or improve patients’ exercise tolerance, teach patients techniques that will help them recover after the procedure, and allow health care providers to identify individuals who might be suboptimal surgical candidates due to noncompliance, poor health, or other reasons.

**Regulatory Status**

N/A

**Scope**

Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

**Benefit Application**

N/A

**Rationale**

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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<tr>
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<td>• Single course of outpatient pulmonary rehabilitation</td>
<td>• Usual care without outpatient pulmonary rehabilitation</td>
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<td>• Quality of life</td>
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<tr>
<td>Individuals: With scheduled lung volume reduction surgery or lung</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
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<td>transplantation</td>
<td>• Single course of outpatient pulmonary rehabilitation</td>
<td>• Usual care without outpatient pulmonary rehabilitation</td>
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<td>Individuals: Who have had lung surgery</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
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<td>• Single course of outpatient pulmonary rehabilitation</td>
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<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
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<td>• Repeat or maintenance outpatient pulmonary rehabilitation</td>
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<td>Individuals: With an indication for outpatient pulmonary rehabilitation</td>
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<td>Comparators of interest are:</td>
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<td>• Single course of ambulatory care–based pulmonary rehabilitation</td>
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This policy is based on a 1996 TEC Assessment. (2) The literature was most recently reviewed using the MEDLINE database through January 27, 2016. Following is a summary of the literature to date.
The focus of this evidence review is on comprehensive, multidisciplinary programs that include an exercise component plus other modalities. Where there is a lack of evidence on multidisciplinary pulmonary rehabilitation (PR) programs, interventions that are strictly exercise will be considered. In this regard, it is considered that exercise constitutes the primary intervention that improves outcomes and that if exercise alone improves outcomes, then it would be expected that exercise plus other modalities will improve outcomes to the same degree or greater.

Initial Course of PR Programs for Patients with Chronic Pulmonary Disease

**Patients with Chronic Obstructive Pulmonary Disease**

Numerous randomized controlled trials (RCTs) and several systematic reviews of RCTs have been published. A 2015 Cochrane review by McCarthy et al included RCTs on the effect of outpatient or inpatient PR on functional and/or disease-specific quality of life (QOL) outcomes in patients with chronic obstructive pulmonary disease (COPD). (3) PR programs had to be at least 4 weeks in duration and include exercise therapy with or without education and/or psychological support. Sixty-five RCTs (total N=3822 participants) met inclusion criteria. COPD severity was not specifically addressed by the Cochrane authors, but article titles reflect a focus on patients with moderate-to-severe COPD. In the pooled analyses, there was statistically significantly greater improvement in all outcomes in the PR groups than in usual care groups. In addition, between-group differences on key outcomes were clinically significant. For example, on all 4 important domains of the Chronic Respiratory Questionnaire (CRQ) —dyspnea, fatigue, emotional function, and mastery—the effect was larger than the accepted minimal clinically important difference (MCID) of 0.5 units. In addition, the between-group difference in maximal exercise capacity exceeded the MCID of 4 watts and the between-group difference in the 6-minute walk distance (6MWD) —a mean difference (MD) of 43.93 meters—was considered clinically significant.

Another Cochrane review, published in 2011 by Puhan et al, selected trials evaluating PR following an acute exacerbation of COPD. (4) To be included, the rehabilitation program needed to begin within 3 weeks of initiating exacerbation treatment and had to include physical exercise. Nine trials (total N=432 participants) met inclusion criteria. Rehabilitation was outpatient in 4 trials, inpatient in 4 trials, and the other trial included both in- and outpatient rehabilitation. In a pooled analysis of 5 trials, there was a statistically significant reduction in the primary outcome (rate of hospital admissions) for PR compared with usual care (odds ratio [OR], 0.22; 95% confidence interval [CI], 0.08 to 0.58). Secondary outcomes also favored the PR group. For example, there was a significant reduction in mortality with PR when findings from 3 studies were pooled (OR=0.28; 95% CI, 0.10 to 0.84). In addition, in a pooled analysis of 6 studies, there was a greater improvement from baseline on the 6MWD in the PR groups (MD=77.7 meters; 95% CI, 12.1 to 143.2).

A 2015 systematic review by Rugbjerg et al identified 4 RCTs (total N=489 participants). (5) Inspection of the study designs in the 4 RCTs indicates that none actually evaluated a comprehensive PR program in patients who met criteria for mild COPD. Rather than being comprehensive PR programs, all interventions were exercise-based. One intervention included an educational component and another used a qigong intervention, which includes breathing and meditation in addition to exercise. In addition, none of the included RCTs selected a patient population only with mild COPD. Roman et al (2013) (6) and Gottlieb et al (2011) (7) included patients with moderate COPD, Liu et al (2012) (8) included patients with mild-to-moderate COPD, and van Wetering et al (2010) (9) included patients with moderate-to-severe COPD. Conclusions cannot be drawn about the efficacy of PR in patients with mild COPD from this systematic review.

**Section Summary: Patients with Chronic Obstructive Pulmonary Disease**

Multiple RCTs and meta-analyses of RCTs have been published and, for the most part, these have found improved outcomes (i.e., functional ability, QOL) in patients with moderate to severe COPD who undergo a comprehensive PR program in the outpatient setting. There is limited evidence on the efficacy of repeated and/or prolonged PR programs, and the available evidence is mixed on whether these programs lead to additional health outcome benefits.

**Patients with Other Chronic Respiratory Diseases**

Patients with chronic lung diseases other than COPD have not been studied as extensively as those with COPD, in large part because of the lower prevalence of these disorders. No RCTs evaluating comprehensive PR programs in this population were published before 2013. A small 2014 pilot RCT by Jackson et al has evaluated
patients with idiopathic pulmonary fibrosis (IPF) who were 40 through 80 years of age and had disease onset between 3 and 48 months before screening, abnormal pulmonary function, and a 6MWD between 150 meters and 500 meters.(10) Patients were assigned to a PR program consisting of twice-weekly 2-hour rehabilitation sessions over 12 weeks (n=14) or usual care (n=11). Twenty-one of the 25 patients completed the 3-month intervention study. The authors did not report between-group p values. Follow-up data at 3 months post intervention were reported by Gaunaud et al.(11) During the intervention, patients in the PR group had significantly greater self-reported physical activity, but, in the subsequent 3 months, activity levels in the 2 groups were similar. For example, at 6 months, pulmonary function measures (eg, total lung capacity, forced vital capacity [FVC], spirometry diffusion capacity) did not change significantly within either group. 6MWD was not reported.

Only observational studies are available in patients with bronchiectasis. In 2011, Ong et al retrospectively compared findings in Australian patients with bronchiectasis (n=69) and an age- and sex-matched group of patients with COPD who attended an outpatient PR program.(12) During the 12-month follow-up period, the 2 diagnosis groups did not differ significantly on the primary outcome measures of 6MWD (p=0.20) or CRQ score (p=0.7). At the 12-month follow-up, the mean between-group difference in 6MWD was 16.1 meters (95% CI, -15.0 to 47.1), and the mean between-group difference in CRQ score was -1.3 points (95% CI, -10.1 to 8.3). This study was not designed to evaluate whether patients with bronchiectasis benefited from PR programs (eg, it did not compare PR with usual care).

**Section Summary: Patients with Other Chronic Respiratory Diseases**

One small RCT evaluating a comprehensive PR program in patients with IPF provides insufficient evidence that PR is effective in this population. RCTs are not available evaluating PR in other non-COPD patients. Observational data suggest that outcomes in patients with other respiratory conditions may benefit, but likely not as much as COPD patients.

**PR Programs before Lung Surgery**

**Lung Volume Reduction Surgery**

PR prior to lung volume reduction surgery (LVRS) represents a distinct subset of patients with COPD, and the National Emphysema Treatment Trial (NETT) requires all candidates to undergo a vigorous course of PR. The final results of the NETT study support treatment effectiveness in a subset of patients with COPD.(13)

**Lung Cancer Resection**

Several small RCTs have evaluated preoperative PR for patients undergoing lung cancer resection. In 2013, Morano et al conducted a single-blind study in Brazil.(14) Patients with non-small-cell lung cancer eligible for lung resection were randomly assigned to 4 weeks of PR (exercise-only, 5 sessions per week) or chest physical therapy; there were 12 patients in each group. All patients in the PR group and 9 of 12 in the chest physical therapy group subsequently underwent surgery (the other 3 patients had inoperable disease). Several short-term postoperative outcomes were assessed. Patients in the PR group spent significantly fewer days in the hospital than patients in the chest physical therapy group (mean, 7.8 days vs 12.2 days; p=0.04). In addition, patients in the PR group spent fewer days with chest tubes than the physical therapy group (mean, 4.5 days vs 7.4 days; p=0.03). The study did not assess longer term functional outcomes after surgery.

In 2011, Benzo et al conducted 2 small exploratory RCTs evaluating PR before lung cancer resection.(15) Eligibility criteria included having moderate-to-severe COPD and being scheduled for lung cancer resection either by open thoracotomy or by video-assisted thoracoscopy. The first study had poor recruitment, enrolling only 9 patients. The second study enrolled 19 patients in to a 10-session, preoperative PR program (n=10) or usual care (n=9). Mean (SD) number of days in the hospital was 6.3 (3.0) in the PR group and 11.0 (6.3) in the control group (p=0.058). Three (33%) patients in the PR group and 5 (63%) patients in the control group experienced postoperative pulmonary complications (p=0.23). The study sample size was likely too small to detect statistically and clinically significant differences between groups. The authors recommended conducting a larger multicenter randomized trial in this population.

In 2013, a non-RCT evaluated an outpatient-based PR intervention in 58 lung cancer patients who were candidates for surgery.(16) This U.K. study by Bradley et al also evaluated a comparison group of 305 patients, also surgical candidates, who received usual care. Patients in the 2 groups were matched by age, lung function, comorbidities, and type of surgery. In a within-group analysis, there was a statistically significant improvement in
the 6MWD of 20 meters in the intervention group before and after participation in a 4-session presurgical PR program. In between-group analyses, there were not statistically significant differences between the intervention and comparisons groups in clinical outcomes such as postoperative pulmonary complications, readmissions, and mortality after surgery.

Section Summary: PR Programs before Lung Surgery
There is a lack of large RCTs comparing PR with no PR for preoperative candidates undergoing LVRS, lung transplantation, or lung cancer resection. However, the NETT study did require PR before LVRS, which is the standard of care before LVRS and lung transplantation. The few small RCTs and observational studies published to date on PR before lung cancer resection have not found consistent evidence of benefit.

PR Programs after Lung Surgery

Lung Volume Reduction Surgery
No studies were identified that evaluated comprehensive PR programs in patients after LVRS. A 2008 review article noted that there is a lack of controlled studies and yet PR is typically provided to patients after LVRS to hasten the recovery process. (17)

Lung Cancer Resection
One RCT, published by Stigt et al. in 2013, evaluated a multicomponent post-surgery PR program in patients with resectable lung cancer. (18) The study was conducted in the Netherlands. Before thoracotomy, 57 patients were randomized to PR (n=23) or usual care (n=26). The 12-week PR program started 4 weeks after surgery and consisted of exercise training, pain management and visits with a medical social worker. The study was terminated early because the institution started offering video-assisted thorascopic surgery, and few patients were choosing thoracotomy. Data on 49 patients were analyzed. The primary end point was QOL, as measured by the difference between groups in change in the total SGRQ score from baseline to 12 months. This difference (SD) was 2.71 (6.90) points and was not statistically significant (p=0.69). However, the 6MWD, a secondary outcome, improved significantly more in the PR group than the usual care group at 3 months. The between-group difference (SD) in 6MWD was 94 (38) meters (p=0.024). A limitation of this analysis is that only 8 of 23 patients in the PR performed a 6MWD at 3 months; the other 15 patients had dropped out or felt unable to take the test. Eleven of 25 patients in the usual care group performed the 6MWD test.

An exercise-only intervention after lung cancer surgery (not comprehensive PR) was evaluated in an RCT published by Edvardsen et al. in 2014. (19) This single-blind study was conducted in Norway and included lung cancer patients 4 to 6 weeks post-surgery. A total of 61 patients were randomized to undergo an exercise program 3 times a week for 20 weeks or usual care. The exercise intervention took place at local fitness centers and was supervised by trained personal trainers and physical therapists. The primary outcome, change in peak oxygen uptake from baseline to the end of the intervention, was significantly greater in the intervention group than the control group (between-group difference, 0.26 L/min; p=0.005). Findings on secondary outcomes were mixed. For example, the between-group difference in FEV1 was 0.6% predicted (95% CI, -4.2 to 5.4; p=0.738) and the difference in stair run was 4.3 steps (95% CI, 1.6 to 7.1; p=0.002). This study did not report other functional outcomes such as 6MWD.

Lung Transplantation
No RCTs evaluating comprehensive PR programs post lung transplantation were identified. In 2009, Munro et al. published findings of a case series in which patients underwent a comprehensive outpatient PR program 1 month after lung surgery. (20) The 7-week program consisted of 1 hour of supervised exercise 3 times a week and a weekly group education session facilitated by various members of a multidisciplinary team (e.g., nurse, dietician, occupational therapist, social worker). Compared with the beginning of the program, on program completion, both FEV1 and FVC improved significantly (p<0.001). For example, mean FEV1 was 71% 1 month post-surgery and 81% at 3 months. Similarly, 6MWD improved significantly; mean distance was 451 meters at 1 month and 543 at 3 months post-transplant. The study is limited by lack of a control group; the degree of improvement that would have occurred without participation in a PR program is not known.

There is literature on exercise training after lung transplantation that is not part of a comprehensive PR program. In 2010, Wickerson et al. published a systematic review of RCTs and nonrandomized studies that evaluated any
type of exercise intervention in lung transplantation. (21) Seven studies met inclusion criteria; 2 were RCTs, 2 were noncontrolled, and 1 used healthy controls. The authors did not pool study findings. The 2 RCTs both evaluated lumbar extension training and its impact on lumbar bone mineral density; neither reported functional outcomes. The uncontrolled studies reported that there were improvements in functional status following exercise interventions.

In 2012, an RCT conducted in the U.K. by Langer et al. examined activity-related outcomes in lung transplant recipients after exercise training. (22) The study included 40 patients between the ages of 40 and 65 years who underwent single or double lung transplantation and had an uncomplicated post-operative period. All patients underwent a standard mobilization program in the hospital after surgery. Following hospital discharge, patients were randomized to undergo a supervised exercise program 3 times a week for 3 months (n=21) or usual care with instructions to exercise (n=19). Patients in both groups had 6 individual counseling sessions in the 6 months after discharge. A total of 6 patients dropped out of the study, 3 in each group.

The primary outcome was daily walking time assessed by activity monitors. At baseline (time of hospital discharge), mean daily walking time (SD) was 36 (16) minutes in the exercise group and 32 (26) minutes in the control group. At the end of the 3 month intervention and 1 year post-discharge, mean walking time was significantly longer in the intervention than control group. At 1 year, the exercise group walked a mean (SD) of 85 (27) minutes per day and the control group walked a mean of 54 (30) minutes per day (p=0.006). Other outcomes related to daily physical activity were reported as secondary outcomes and some, but not all, significantly favored the intervention group. The mean (SD) 6MWD at 1 year was 86% (7) of predicted in the exercise group and 74% (11) of predicted in the control group (p=0.002). The study had a relatively small sample size and may have been underpowered to detect clinically meaningful differences between groups on secondary outcomes.

Section Summary: PR Programs after Lung Surgery
For postsurgical comprehensive PR, only 1 small RCT was identified. The RCT included patients who underwent thoracotomy for lung cancer, was terminated early, and had mixed findings. There were also several small RCTs evaluating exercise training after lung surgery. One of these, conducted in lung transplant recipients, reported physical activity outcomes and found a significant benefit of a 3-month exercise training program compared with usual care on daily walking time and some secondary outcomes.

Repeat and Maintenance PR Programs
Both repeat and maintenance PR programs provide additional rehabilitation services after initial participation in a PR program. Program categories are not strictly defined but repeat programs are generally considered to be those that include patients who failed to respond to an initial program or whose response to an initial rehabilitation program has diminished over time. In contrast, maintenance programs tend to be those designed to extend the effects of the initial PR program, and they are open to all patients who successfully completed an initial program.

Repeat PR Program
One RCT was identified that evaluated a repeat PR program. Carr et al prospectively identified Canadian patients with moderate-to-severe COPD who experienced an acute exacerbation within 12 months of participating in a PR program. (23) Initially, patients completed a 6-week inpatient program or a 12-week outpatient program. The repeat PR program lasted 3 weeks and consisted of exercise and education; patients could choose inpatient or outpatient versions. Over 6 months, 41 patients developed an exacerbation and 12 did not. Seven patients withdrew from the study, and the remaining 34 were randomly assigned to a repeat PR program within 1 month of the exacerbation (n=17) or to no repeat PR program (n=17). One patient in the intervention group dropped out; of the remaining 33 patients, 25 (76%) experienced an exacerbation of moderate severity; the remaining 8 had severe exacerbations. Nine (56%) of 16 patients in the intervention group chose an inpatient program and 7 chose an outpatient program. Patients were assessed before the repeat PR program, immediately after (3 weeks later), and again 12 weeks after the beginning of the exacerbation (~5 weeks after completing the repeat rehabilitation program). The primary outcome was change in health-related quality of life, as measured by the CRQ, a validated measure with 4 domains. There was no statistically significant difference between groups in mean change in CRQ scores. Among patients in the intervention group, the magnitude of improvement in the domains of dyspnea (0.7±1.5 points) and fatigue (0.5±1.3 points) met or exceeded the minimum clinically important difference (MCID). In the control group, the magnitude of change in all dimensions did not meet the MCID. Change in the 6MWD, a secondary outcome, did not differ significantly between groups at either follow-up. Outcomes were not reported separately for the inpatient or outpatient programs (this evidence review addresses outpatient programs). The authors recommended that future evaluations of repeat PR programs include patients
with more serious exacerbations, last longer than 3 weeks, and start as close in time as possible to the exacerbation. Conclusions about repeat PR programs cannot be drawn from 1 study with 33 subjects.

**Maintenance PR Program**

In 2012, an Ontario Health Technology Assessment was published on PR for patients with COPD. (24) The review identified 3 RCTs (total N=284 participants) evaluating maintenance PR programs for individuals with COPD who successfully completed an initial PR program. The studies excluded patients who had experienced a recent acute exacerbation of COPD. The maintenance programs all consisted of supervised exercise sessions; program duration was 3 months in 1 program and 12 months in the other 2 programs. One program also included an unsupervised exercise component, and 1 included educational sessions. The reviewers judged the quality of the studies as generally poor due to methodologic limitations such as inadequate information on randomization, allocation concealment and blinding and lack of clarity around the use of an intention-to-treat analysis. In a pooled analysis of data from 2 of the studies (total N=168), there was a significantly greater 6MWD in patients who participated in the maintenance program compared with those in a control group (mean difference, 22.9 meters; 95% CI: 5.2 to 40.7). The CI: was wide, indicating lack of precision in the pooled estimate. In addition, the review authors considered the minimal clinically important difference in meters walked to be 25 to 35 meters, and the meta-analysis of study findings did not meet this threshold of difference between groups.

In 2015, Wilson et al published a single-blind RCT comparing maintenance PR to standard care without maintenance PR in patients with COPD who had completed at least 60% of an initial PR program. (25) One hundred forty-eight patients were randomized; 110 (74%) completed the study and were included in the analysis. The maintenance program consisted of a 2-hour session every 3 months for 1 year. The session included an hour of education and an hour of supervised individualized exercise training. The primary efficacy outcome was change from baseline (post-PR) in the dyspnea domain of the CRQ. Among study completers, the mean (SD) CRQ dyspnea score changed from 2.6 (1.0) to 3.2 (1.1) among patients receiving maintenance PR and from 2.5 (1.2) to 3.3 (1.3) among controls. The difference between groups was not statistically significant. Secondary outcomes, including other domains of the CRQ, scores on the endurance shuttle walk test (ESWT), and number of exacerbations or hospitalizations, also did not differ significantly between groups.

**Section Summary: Repeat and Maintenance PR Programs**

A few small RCTs have been performed that evaluate repeat or maintenance rehabilitation programs. Due to the small number of RCTs, methodologic limitations of available studies, and lack of clinically significant findings, the evidence to determine the effect of repeat and maintenance PR programs on health outcomes in patients with COPD is insufficient.

**Home-based PR Programs**

Evaluation of home-based PR programs involves searching for evidence that these are at least as effective as programs conducted in the ambulatory care setting. The programs also need to be comprehensive PR programs and be feasible in the context of the U.S. health care system.

Several RCTs and systematic reviews of RCTs have been published on home-based PR programs. Among the systematic reviews, Liu et al. in 2013 identified 18 RCTs evaluating home-based PR programs. (26) Most studies compared PR with usual care, and none of the included trials compared home-based and clinic-based programs. Only 2 of the 18 studies were conducted in the United States, and both of those were published in the 1990s. The studies reported different outcomes in over different timeframes, and pooled analysis only included data from 2 to 4 studies. For example, a pooled analysis of 3 studies with a total of 112 patients reporting the SGRQ total score found statistically significant improvement in symptoms with home-based PR compared with control (effect size, -11.33; 95% CI: -16.37 to -6.29). A pooled analysis of data from 4 studies (N=167) found a significantly increased 6MWD after 12 weeks in the PR group compared with control (effect size, 35.9; 95% CI: 9.4 to 62.4). The latter analysis had a wide CI: indicating that estimate of effect was not precise.

Previously, a 2010 systematic review by Vieira et al. identified 12 RCTs comparing home-based PR with PR in another setting or to standard care in patients with COPD. (27) The comparison intervention in 3 studies was a hospital-based program, in 8 studies was standard care, and 1 study had both types of comparisons. The methodologic quality of the studies was considered to be average to poor, and most had small sample sizes and relatively short follow-up duration. The authors did not pool study findings and findings of individual studies were mixed. Three studies that compared home-based PR with standard care reported data on between-group
differences in QOL; in all 3 studies, differences were reported as statistically significant. The 2 studies that reported differences in exercise capacity found home-based PR to result in significantly greater improvement in the 6MWD or constant work rate test than standard care. On the other hand, in the 3 studies comparing home-based PR and hospital-based programs, there were no statistically significant differences between groups in quality-of-life changes. Moreover, in the 2 studies that assessed maximal work level and the 2 studies that assessed the 6MWD, outcomes did not differ significantly after home-based or hospital-based PR programs. The authors commented that the review was limited by the generally low quality of the randomized trials and that most studies had only short-term follow-up.

A study with a relatively large sample size, and that compared home-based PR with outpatient clinic-based PR was published by Maltais et al. in 2008. (28) This was a noninferiority trial and was conducted in Canada. Eligibility criteria included stable COPD for at least 4 weeks before study participation and no previous participation in PR programs; 252 patients were included. All patients initially completed a 4-week self-management educational program. They were then randomized to receive 8 weeks of either self-monitored home-based exercise training or outpatient hospital-based exercise training. The exercise program included aerobic and strength exercises conducted 3 times per week. Patients were followed up for 40 weeks after completion of the exercise program. Both interventions produced similar improvements in the CRQ Dyspnea subscale at 1 year: improvement in dyspnea of 0.62 (95% CI: 0.43 to 0.80) units in the home intervention (n=107) and 0.46 (95% CI: 0.28 to 0.64) units in the outpatient intervention (n=109). The difference between treatments at 1 year was considered clinically unimportant. The study did not evaluate a comprehensive PR program.

Section Summary: Home-based PR Programs
Most studies of home-based PR compared outcomes with standard care. There are very few studies that compare home-based PR with hospital or clinic-based PR and the available studies are mostly of low quality. Therefore, there is insufficient evidence that comprehensive PR programs conducted in the home setting are at least as effective as comprehensive PR programs in the ambulatory care setting.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<td>Ongoing</td>
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<td>NCT02017925</td>
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<td>Pulmonary Rehabilitation in Asthmatic Patient</td>
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<td>NCT02044939</td>
<td>Pulmonary Rehabilitation in Patients With Sarcoidosis</td>
<td>150</td>
<td>Jul 2017</td>
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</tbody>
</table>

NCT: national clinical trial

Summary of Evidence
The evidence for a single course of outpatient pulmonary rehabilitation (PR) in individuals who have moderate-to-severe chronic obstructive pulmonary disease (COPD) includes numerous randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. The published studies found improved outcomes (i.e., functional ability, quality of life) in patients with moderate-to-severe COPD who undergo a comprehensive PR program in the outpatient setting. Among the many randomized trials, the structure of the PR programs varies, so it is not possible to provide guidance on the optimal components or duration of a PR program. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for a single course of outpatient PR in individuals who have scheduled lung volume reduction surgery (LVRS) or lung transplantation includes RCTs and observational studies. Relevant outcomes are symptoms, functional outcomes, and quality of life. Few large RCTs have compared PR with no PR for preoperative candidates undergoing LVRS, lung transplantation, or lung cancer resection. However, a key trial did find benefit of LVRS in select patients who required PR before LVRS (PR is the standard of care before LVRS and lung transplantation). The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.
The evidence for a single course of outpatient PR in individuals who have had lung surgery includes 1 RCT of a comprehensive PR program. Relevant outcomes are symptoms, functional outcomes, and quality of life. The RCT, which included patients who underwent thoracotomy for lung cancer, was terminated early and had mixed findings. The evidence is insufficient to determine the effects of the technology on health outcome.

The evidence for repeat or maintenance outpatient PR in individuals who have had a previous course of PR includes RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. There are only a few RCTs and many of many have methodologic limitations and/or did not have clinically significant outcomes. The evidence is insufficient to determine the effects of the technology on health outcome.

The evidence for a single course of home-based PR in individuals who have an indication for outpatient PR includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. Most studies of home-based PR have compared outcomes with standard care. Very few have compared home-based PR with hospital- or clinic-based PR, and the available studies are mostly of low quality. The evidence is insufficient to determine the effects of the technology on health outcome.

Practice Guidelines and Position Statements

**American Thoracic Society and European Respiratory Society**

A 2013 joint statement on PR was issued by the American Thoracic Society (ATS) and the European Respiratory Society (ERS). (1) The statement included the following relevant conclusions:

- PR provided to patients with respiratory disease other than COPD has demonstrated improvement in respiratory symptoms, exercise tolerance and quality of life.
- “Symptomatic individuals with COPD who have lesser degrees of airflow limitation who participate in rehabilitation derive similar improvements in symptoms, exercise tolerance and quality of life as do those with more severe disease.”
- Appropriately designed home-based exercise training has been found to be effective at reducing dyspnea and increasing exercise performance in patients with COPD.

**British Thoracic Society**

A 2013 guideline on PR in adults by the British Thoracic Society includes the following recommendations (29):

- PR should be offered to patients with COPD to improve exercise capacity, dyspnea, health status and psychological wellbeing.
- PR programs of 6 to 12 weeks in duration are recommended. A minimum of 12 supervised sessions are recommended, although some patients may gain benefit from fewer sessions.
- If considering a home-based program, the following factors need careful consideration: patient selection, means of providing remote support and/or supervision and provision of home exercise equipment.

**American College of Chest Physicians et al**

A 2011 joint guideline on management of COPD was issued by the American College of Physicians, the American College of Chest Physicians (ACCP), ATS, and ERS (30): The guideline recommends that “clinicians should prescribe pulmonary rehabilitation for symptomatic patients with an FEV [forced expiratory volume] <50% predicted (Grade: strong recommendation, moderate-quality evidence). Clinicians may consider pulmonary rehabilitation for symptomatic or exercise-limited patients with an FEV >50% predicted (Grade: weak recommendation, moderate-quality evidence).”

**American College of Chest Physicians et al**

In 2007, a joint guideline on PR for COPD and other chronic respiratory diseases was issued by ACCP and the American Association of Cardiovascular and Pulmonary Rehabilitation. (31) The panel issued a number of recommendations. Following are the strong recommendations based on strong (1A) or moderate (1B) evidence:

**Grade of Recommendation 1A**

- A program of exercise training of the muscles of ambulation is recommended as a mandatory component of pulmonary rehabilitation for patients with COPD.
- Pulmonary rehabilitation improves the symptom of dyspnea and improves health-related quality of life in
patients with COPD.

- Six to 12 weeks of pulmonary rehabilitation produces benefits in several outcomes that decline gradually over 12 to 18 months.
- Both low- and high-intensity exercise training produce clinical benefits for patients with COPD.
- "Unsupported endurance training of the upper extremities is beneficial in patients with COPD and should be included in pulmonary rehabilitation programs."

**Grade of Recommendation 1B**

- "Higher-intensity exercise training of the lower extremities produces greater physiologic benefits than lower-intensity training in patients with COPD.
- "Evidence does not support the routine use of inspiratory muscle training as an essential component of pulmonary rehabilitation."
- "Education should be an integral component of pulmonary rehabilitation; it should include information on collaborative self-management and prevention and treatment of exacerbations."
- "Pulmonary rehabilitation is beneficial for some patients with chronic respiratory diseases other than COPD.

**References**


Appendix

N/A
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<tr>
<td>08/11/15</td>
<td>New Policy. Add to Rehabilitation Therapy. Policy created with literature review. Considered medically necessary when criteria are met.</td>
</tr>
<tr>
<td>05/10/16</td>
<td>Annual review. Policy updated with literature review through January 27, 2016; references 3, 5-9, and 25 added. Policy statements unchanged.</td>
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